REMARKS

In response to the Office Action mailed October 19, 2007, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following remarks.

Summary of the Office Action

In the October 19, 2007 Office Action, Claims 1-8 stand rejected. Claims 9-22 were withdrawn from consideration. Claims 1, 2, 4-8 stand rejected by the Examiner under 35 U.S.C. § 112, first paragraph. Next, Claims 1, 2, 4-8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,945,409 issued to Crandall (hereinafter "Crandall"). Therefore, Claims 1-8 currently remain pending.

Summary of the Amendment

Upon entry of this amendment, Applicant will have amended Claim 1. Accordingly, Claims 1-8 are currently pending. Please note that in the amendments to the claims, deletions are indicated by strikethrough (e.g. ~~deletion~~) or double brackets (e.g. [[word]]) and additions to the claims are underlined (e.g. addition). Applicants respectfully submit that the present application is in condition for allowance.

Traversal of Rejection under 35 U.S.C. § 112, First Paragraph

In the Office Action, Claims 1, 2, 4-8 stand rejected by the Examiner under 35 U.S.C. § 112, first paragraph, based on the allegation that the specification, while being enabling for C-6 ceramide as the hydrophobic therapeutic agent, does not reasonably provide enablement for all hydrophobic thereapeutics.

Applicant respectfully traverses this rejection. First, Applicant respectfully points out that the method of preparing the coating formulation comprising the hydrophobic therapeutic agent, the non-volatile oil-based solvent, and the volatile solvent is simple and certainly described with sufficient particularity to enable a skilled practitioner to make the recited coating formulation with any of the exemplary hydrophobic agents, see e.g., those identified in paragraph **[0022]**. The specification provides ample guidance to the skilled practitioner for preparing the

coating formulation, see e.g., paragraph **[0019]**, teaching that one exemplary hydrophobic agent, C6-ceramide, was sufficiently soluble and/dispersible in non-volatile oil-based formulations when all components were first dissolved in a volatile solvent, such as ethanol. Similarly, in Example 2, the non-volatile oil-based solvent (1% vitamin E, 0.5% propylene glycol and 0.05% Myrj 52) is mixed with 0.5% (w/w) C6-ceramide dissolved in ethanol. Further, original Claim 16 sets forth the simple method as "producing a coating composition by mixing a drug composition comprising a drug and an oil-based non-volatile solvent in a volatile solvent."

Indeed, an advantage of the recited method resides in its simplicity. In other drug eluting technologies, the therapeutic agent is incorporated and/or entrapped in particulate form within complex elastomeric matrices (see e.g., U.S. Patent No. 5,837,313 to Ding et al., which discloses a method of incorporating a biologically active particulate material having an average particle size of 15 microns into at least one layer of the coating and applying the elastomeric coating in a manner which adheringly conforms to the surface of the prosthesis; and then curing the coating such that at least some of the biologically active material is particulate after curing). In contrast, use of the present coating formulation "...works to keep a lipid material in a very deliverable form without further solid-state changes that could lead to ineffective delivery (paragraph **[0027]**).

The Schultz Declaration, filed herewith, further supports both the simplicity of the present method as well as its applicability to other hydrophobic therapeutic agents besides C6-ceramide. As demonstrated by Dr. Schultz, when C6-ceramide was substituted with rapamycin (another hydrophobic active), the coating formulation made in accordance with the teaching of the specification was easy to prepare and effective in coating an angioplasty balloon with rapamycin, wherein the drug eluted from the balloon in a predictable, time-dependent manner. Thus, Applicant respectfully asserts that one of skill in the art could readily formulate any hydrophobic agent for coating in accordance with preferred aspects of the present invention simply by mixing the agent with a non-volatile oil-based solvent, such as Vitamin E, and a volatile solvent, such as ethanol. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of Claims 1, 2, 4-8 based on lack of enablement for the full scope of the claimed invention, and in particular, for the genus of hydrophobic therapeutic agents.

Traversal of Rejection under 35 U.S.C. § 102(b)

In the Office Action, 1, 2, 4-8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Crandall. While Applicants reserve the right to prosecute these claims as originally filed, Applicants have amended Claim 1 in order to expedite prosecution of this Application. Accordingly, Applicants respectfully request that the rejection of Claims 1, 2, 4-8 be withdrawn and that these claims be indicated as allowable over the art of record.

Claim 1 now recites, *inter alia*, a "formulation for coating a medical device with a hydrophobic therapeutic agent, comprising the hydrophobic therapeutic agent, a non-volatile oil-based solvent other than lecithin, and an amount of a volatile solvent sufficient to decrease the viscosity of the non-volatile oil-based solvent."

In contrast, Crandall is directed to a formulation comprising lecithin. *See* Crandall, col. 4, lines 18-30; *see also* Office Action, page 3. Crandall indicates that its method of moisturizing is performed with "a composition comprising lecithin, in an organic solvent and water whereby the composition is delivered into the stratum corneum, epidermis and dermis." Crandall, col. 2, lines 55-60. Further, Crandall indicates that the composition can comprise a "water dispersible lecithin." *Id.* at col. 2, lines 60-65. Crandall emphasizes the importance of the use of lecithin in its composition, and while it indicates that other phospholipids can be used, Crandall never discloses that the composition can be made without the use of lecithin. *See id.* at col. 4, lines 31-58. Accordingly, Applicant respectfully submits that Crandall does not disclose a formulation that uses "a non-volatile oil-based solvent other than lecithin," as recited in Claim 1.

Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claim 1, as well as Claims 2 and 4-8, which depend from Claim 1, and indicate that these claims are allowable over the art of record.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other

broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

Applicant respectfully submits that the above rejections and objections have been overcome and that the present application is now in condition for allowance. Therefore, the Applicant respectfully requests that the Examiner indicate that Claims 1-8 are now acceptable and allowed. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

Applicant respectfully submits that the claims are in condition for allowance in view of the above remarks. Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claim and drawings in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the Applicant's attorney in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 1/22/08

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